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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/806,288	03/23/2004	Bengt Guss	GUSS3001D/JDB	1848

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EXAMINER

DEVI, SARVAMANGALA J N

ART UNIT	PAPER NUMBER
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1645

DATE MAILED: 03/21/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No. 10/806,288	Applicant(s) GUSS BENGT	
	Examiner S. Devi, Ph.D.	Art Unit 1645	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 19 August 2004.
- 2a) ☐ This action is FINAL. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 30-35 ~~is/are~~ are pending in the application.
- 4a) Of the above claim(s) 31-35 ~~is/are~~ are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 30 ~~is/are~~ rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☒ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 30 April 2004 is/are: a) ☒ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☒ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☒ Certified copies of the priority documents have been received in Application No. 09/147,405.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date <u>3/23/04</u> . | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION
Preliminary Amendment

1) Acknowledgment is made of Applicants' preliminary amendment filed 03/24/04 and Applicants' response filed 12/15/04. With this, Applicants have amended the specification.

Election

2) Acknowledgment is made of Applicants' election filed 08/19/04 in response to the restriction requirement mailed 07/23/04. Applicants have elected invention I, claim 30, and the antibody species raised against the polypeptide of SEQ ID NO: 13, with traverse. Applicants state that their traversal is with respect to the election of species. Applicants submit that SEQ ID NO: 13 is a shorter version of the protein sequence, SEQ ID NO: 15. Applicants state of their understanding that once the elected species is found allowable, the search will extend to the other species, and the process claims would be rejoined.

Applicants' arguments have been carefully considered. Upon further consideration, antibodies to both the sequence species, SEQ ID NO: 13 and SEQ ID NO: 15 in claim 30, have been searched and examined. As clearly set forth in the restriction requirement mailed 08/23/04, in the event of rejoinder, to be allowable, the rejoined claims must meet all criteria for patentability including the requirements of 35 U.S.C. § 101, 102, 103 and 112, which includes enablement. Withdrawn process claims that are not commensurate in scope with an allowed product claim will not be rejoined. See 'Guidance on Treatment of Product and Process Claims in light of *In re Ochiai*, *In re Brouwer* and 35 U.S.C § 103(b),' 1184 O.G. 86 (March 26, 1996). Additionally, in order to retain the right to rejoinder in accordance with the above policy, Applicant is

advised that the process claims should be amended during prosecution either to maintain dependency on the product claims or to otherwise include the limitations of the product claims. Failure to do so may result in a loss of the right rejoinder.

Status of Claims

- 3) Claims 1-29 have been canceled via the preliminary amendment filed 03/23/04. New claims 30-35 have been added via the preliminary amendment filed 03/23/04. Claims 30-35 are pending. Claims 31-35 are withdrawn from consideration as being directed to non-elected inventions. See 37 C.F.R 1.142(b) and M.P.E.P § 821.03.

Claim 30 is under examination. A First Action on the Merits on these claims is issued.

Information Disclosure Statement

- 4) Acknowledgment is made of Applicants' information disclosure statement filed 03/23/04. The duplicate citation of McDevitt *et al.*, 1991, has been lined through. The information referred to therein has been considered and a signed copy is attached to this Office Action.

Sequence Listing

- 5) Acknowledgment is made of Applicants' submission of the raw sequence listing and the CRF which have been entered on 6/30/04.

Priority

- 6) The instant application is a Divisional application of application SN 09/147,405, filed 04/01/1999, now U.S. patent 6,733,758, which is a 371 application of PCT/SE97/01901, filed 06/18/1997 and claims foreign priority to the application

9602496, filed 06/20/1996 in Sweden.

Title

7) The title of the invention is not descriptive. A new title reflective of the elected claim --Antibodies to a fibrinogen binding protein of *Staphylococcus epidermidis*-- is suggested.

Non-Compliance with Sequence Rules

8) The replacement filed 04/30/04 for the section 'Sequence list' on the original pages 19-21 of the specification appear to represent a nucleotide sequence longer than ten nucleotide bases in length and an amino acid sequence longer than four amino acids in length as indicated at the bottom of page 17 of the specification. Yet the amendment to this section of the specification filed 04/30/04 does not identify both the sequences with specific SEQ ID numbers, as required under 37 C.F.R 1.821 through 1.825.

Similarly, Figures 6A-6E, as amended via the amendment filed 04/30/04, represent a nucleotide sequence and an amino acid sequence as indicated via the amended specification beginning at line 2 of page 2. Yet the amendment to this section of the specification filed 04/30/04 does not identify both the sequences with specific SEQ ID numbers, as required under 37 C.F.R 1.821 through 1.825. The brief description for Figures 6A-6E states that the figures show the complete nucleotide sequence of the *fig* gene and the deduced amino acid sequence of the encoded protein, yet identifies only one of these sequences by a sequence identifier, i.e., SEQ ID NO: 14. Every amino acid sequence recited in the specification that is longer than four amino acids and every nucleotide sequence recited in the specification that is longer than ten nucleotide bases *must* be identified by a SEQ ID number as required under 37 C.F.R 1.821 through 1.825.

If not included already, such SEQ ID numbers should be included in the raw Sequence Listing.

Specification - Informality

9) The specification is objected to for the following reasons:

(a) The first paragraph of the specification does not provide the priority information as indicated above under the section 'Priority'. Amendment to the specification is requested.

(b) The amendment (filed 04/30/04) to the specification beginning at line 6 of page 10 is objected to under 35 U.S.C. § 132, because it introduces new matter into the disclosure. 35 U.S.C. § 132 states that no amendment shall introduce new matter into the disclosure of the invention. The added material which is not supported by the original disclosure is as follows. The recitation 'at amino acid locations 1053-1057', added to the specification at the paragraph beginning on page 10, line 6 via the amendment filed 04/30/04, is new matter. Applicants are required to cancel the new matter in the response to this Office Action. Since the recited amino acid motif is already shown in bold in Figure 6, it is suggested that Applicants delete the recitation 'at amino acid locations 1053-1057'.

(c) The raw sequence listing in the instant application includes SEQ ID NO: 10, SEQ ID NO: 11, SEQ ID NO: 12, SEQ ID NO: 13 and SEQ ID NO: 15. However, the instant specification lacks antecedent basis or descriptive support for SEQ ID NO: 10; SEQ ID NO: 11; SEQ ID NO: 12, SEQ ID NO: 13 and SEQ ID NO: 15.

(d) The brief description for Figure 6A-6E states that the figures show both the nucleotide sequence of the *fig* gene and the deduced amino acid sequence of the encoded

protein, but identifies only one of the sequences as SEQ ID NO: 14. The other sequence should also be identified by a SEQ ID number. Additionally, the current description appears to incorrectly identify the deduced amino acid sequence of the encoded protein to be 'SEQ ID NO: 14', whereas the raw Sequence Listing filed in the application identifies SEQ ID NO: 14 to be a 'DNA' as opposed to a protein. Correction/clarification is requested.

Rejection(s) under 35 U.S.C. § 101

10) 35 U.S.C. § 101 states:

Whoever invents or discovers any new and useful process, machine, manufacture, or composition of matter, or any new and useful improvement thereof, may obtain a patent therefor, subject to the conditions and requirements of this cycle.

11) Claim 30 is rejected under 35 U.S.C. § 101 as being directed to a non-statutory subject matter. The recitation 'Antibodies' in line 1 of claim 30 reads on a product of nature, i.e., naturally occurring antibodies to the protein or polypeptide present on the surface of a naturally occurring *Staphylococcus epidermidis*. Claim 30 lacks limitations, which distinguish the product from those that may exist naturally. Consequently, the claim does not embody patentable subject matter as defined in 35 U.S.C § 101. In the absence of the hand of man, the naturally occurring products are considered non-statutory subject matter. See *Diamond v. Chakrabarty*, 447 U.S. 303, 206 USPQ 193 (1980). It is suggested that Applicants use a limitation, such as, --isolated--, in connection with the antibody product to reflect the hands of the inventors in the production or creation of the recited product, if such a limitation is supported in the instant specification. See MPEP 2105.

Rejection(s) under 35 U.S.C. § 112, First Paragraph

12) Claim 30 is rejected under 35 U.S.C. § 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. This is a new matter rejection.

New claim 30 is drawn to antibodies 'raised against a *Staphylococcus epidermidis* protein having the amino acid sequence of SEQ ID NO: 15'. Applicants point to page 4, line 30 to line 1, page 5; Example 12; and Figures 10 and 11 as providing descriptive support for the new claim. However, while there appears to be descriptive support in these parts of the specification for antibodies against *Staphylococcus epidermidis* protein having fibrinogen binding activity and the amino acid sequence of SEQ ID NO: 13, or a fusion protein comprising the amino acid sequence of SEQ ID NO: 13, there appears to no support for antibodies against the protein of the amino acid sequence, SEQ ID NO: 15, or a fusion protein comprising the amino acid sequence of SEQ ID NO: 15. Therefore, the above-identified limitations in the claim are considered to be new matter. *In re Rasmussen*, 650 F2d 1212 (CCPA, 1981). New matter includes not only the addition of wholly unsupported subject matter but also, adding specific percentages or compounds after a broader original disclosure, or even omission of a step from a method. See M.P.E.P 608.04 to 608.04(c).

Applicants are respectfully requested to point to the descriptive support in the specification as filed, for the newly added limitation(s), or to remove the new matter from the claim(s).

Rejection(s) under 35 U.S.C. § 102

13) The following is a quotation of the appropriate paragraphs of 35 U.S.C. § 102 that form the basis for the rejections under this section made in this Office Action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

14) Claim 30 is rejected under 35 U.S.C § 102(b) as being anticipated by Palker *et al.* (*PNAS* 85: 1932-1936, 1988) as evidenced by McGuinness *et al.* (*Mol. Microbiol.* 7: 505-514, 1993).

It is noted that the claimed antibodies are not required to be isolated and/or purified. The claimed antibodies are not required to bind specifically to the purified SEQ ID NO: 15 or 13. Non-isolated antibodies induced by whole cells of *Staphylococcus epidermidis* would read on the claim.

Palker *et al.* taught antibodies raised by immunization of goats with an antigenic conjugate composition comprising a synthetic peptide with the sequence Asn-Asn-Thr (NNT), i.e., peptide, chemically fused to a protein carrier, such as, BSA or tetanus toxoid. See abstract; Materials and Methods; Results; Figure 1 and Table 1. The NNT peptide contained in the Palker's synthetic peptide immunogen is the same peptide, NNT, present at amino acid positions 403-404 of the instantly recited SEQ ID NO. 15, or at amino acid positions 329-331 of the instantly recited SEQ ID NO: 13, and therefore the prior art antibodies to the NNT-containing peptide are expected to bind to the instantly recited SEQ ID NO: 15 or SEQ ID NO: 13 which contains the NNT peptide.

That the peptide NNT present in the prior art peptide-protein carrier conjugate

constitutes an epitope of a bacterial protein is inherent from the teachings of Palker *et al.* in light of what is well known in the art. For instance, McGuinness *et al.* identified the peptide sequence, NNT, to be the epitope recognized by the P1.15-specific monoclonal antibody (see Table 1).

The teachings of Palker *et al.* anticipate the instant claim. McGuinness *et al.* is not used as a secondary reference in combination with Palker *et al.*, but rather is used to show that every element of the claimed subject matter is disclosed by Palker *et al.* with the unrecited limitation(s) being inherent in view of what is known in the art as explained above. See *In re Samour* 197 USPQ 1 (CCPA 1978).

The term 'raised against' in the claim represents a process limitation in the product claim. When claims are drawn to a product-by-process, claims are not limited to the manipulations of the recited step(s), but only the structure implied by the steps. MPEP § 2113 states:

[E]ven though product-by-process claims are limited by and defined by the process, determination of patentability is based on the product itself. The patentability of a product does not depend on its method of production. If the product in the product-by-process claim is the same as or obvious from a product of the prior art, the claim is unpatentable even though the prior product was made by a different process. *In re Thorpe*, 777 F.2d 695, 698, 227 USPQ 964, 966 (Fed. Cir. 1985) (citations omitted).

A product does not have to be made by the same process in order to be the same product, because a product is a product, no matter how it is claimed. Applicants have not shown that the alleged difference(s) in the process results in a product that is structurally different from the product of the prior art. In the instant case, Applicants have not shown that the underlying structure of the prior art antibodies

differs from that of the instantly claimed antibodies.

Objection(s)

15) Claim 30 is objected to for reciting a bacterial name, 'Staphylococcus epidermidis' without italicizing. To be consistent with the practice in the art, it is suggested that Applicants replace the recitation with --*Staphylococcus epidermidis*--.

Remarks

16) Claim 30 stands rejected.

17) Papers related to this application may be submitted to Group 1600, AU 1645 by facsimile transmission. Papers should be transmitted via the PTO Fax Center, which receives transmissions 24 hours a day and 7 days a week. The transmission of such papers by facsimile must conform with the notice published in the Official Gazette, 1096 OG 30, November 15, 1989. The RightFax number for submission of amendments, responses or papers is (571) 273-8300.

18) Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAG or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.Mov>. Should you have questions on access to the Private PAA system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

19) Any inquiry concerning this communication or earlier communications from the Examiner should be directed to S. Devi, Ph.D., whose telephone number is (571) 272-0854. A message may be left on the Examiner's voice mail system. The Examiner can normally be reached on Monday to Friday from 7.15 a.m. to 4.15 p.m. except one day

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each bi-week, which would be disclosed on the Examiner's voice mail system.

If attempts to reach the Examiner by telephone are unsuccessful, the Examiner's supervisor, Lynette Smith, can be reached on (571) 272-0864.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the Group receptionist whose telephone number is (571) 272-1600.

March, 2005


S. DEVI, PH.D.
PRIMARY EXAMINER